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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,535	06/03/2005	Eric Thomas McAdams	960002	4773

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EXAMINER	
DANEGA, RENEE A	
ART UNIT	**PAPER NUMBER**
3736	
MAIL DATE	**DELIVERY MODE**
09/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,535	MCADAMS, ERIC THOMAS	
	Examiner	Art Unit	
	Renee Danega	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 31-37, 39-42, 47, 48, and 50-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Pearlman (US 6308097).

- Regarding claims 31-32, Pearlman teaches a tissue measurement system comprising a two dimensional array of test electrodes (141) for application to a surface of tissue under investigation, circuit means (142) for measuring an electrical characteristic of the tissue underlying each test electrode and means for presenting at least one value representing a physical characteristic (16) of at least one region of tissue based on the measured electrical characteristics; the physical characteristic being area (Figures 1, 7B, 14) (column 4, lines 3-22) (column 21, lines 37-52)
- Regarding claim 33, Pearlman teaches the presenting means to be capable of presenting a plurality of values on a display device to provide a visual map representing the physical extent of the region of tissue (Figure 14).

- Regarding claim 34, Pearlman teaches the array of test electrodes to be on a flexible backing of insulating material (column 8, lines 40-45) (column 10, lines 1-7).
- Regarding claim 35, Pearlman teaches the array of electrodes to be rectangular (Figure 7B).
- Regarding claims 36-37, Pearlman teaches each test electrode to be covered in a hydrogel, the resistant being relatively high to each other relative to the resistance via the gel to the skin (column 9, lines 39-52).
- Regarding claim 39, Pearlman teaches the two-dimensional array to comprise at least 25 test electrodes (141) (Figure 7B).
- Regarding claim 40, Pearlman teaches the electrical characteristic to be the impedance underlying each test electrode (abstract) (column 1 lines 16-18).
- Regarding claim 41, Pearlman teaches the circuit means capable of measuring the electrical characteristic by applying an alternating signal between the test electrode and at least one other electrode applied to the organic body of which the tissue forms a part (column 29 line 66- column 30 line 32).
- Regarding claim 42, Pearlman teaches the circuit means capable of measuring the electrical characteristic by measuring voltage between each test electrode and adjacent reference electrode (column 25, lines 30-48).

- Regarding claim 44, Pearlman teaches a single reference electrode common to a plurality of test electrodes (column 29 line 66- column 30 line 32).
- Regarding claim 47, Pearlman teaches each test electrode measuring at a plurality of different frequencies (column 21, lines 14-28).
- Regarding claim 48, Pearlman teaches the or each measurement is made at a frequency of 1 mHz to 100 kHz (column 21, lines 14-28).
- Regarding claim 50, this claim states the steps of the method performed by the apparatus of claim 31, thus the same rationale of rejection is applicable.
- Regarding claim 51, Pearlman teaches the physical characteristic is area (Figures 14, 15).
- Regarding claim 52, Pearlman teaches the presenting means to be presenting a plurality of values on a display device to provide a visual map representing the physical extent of the region of tissue (Figure 14).
- Regarding claim 53, Pearlman teaches the array of test electrodes to be arranged on a flexible backing of insulating material (column 8, lines 40-45) (column 10, lines 1-7).
- Regarding claim 54, Pearlman teaches each test electrode to be covered in a hydrogel, the resistant being relatively high to each other relative to the resistance via the gel to the skin (column 9, lines 39-52).

- Regarding claim 55, Pearlman teaches the two-dimensional array to comprise at least 25 test electrodes (141) (Figure 7B).
- Regarding claim 56, Pearlman teaches the electrical characteristic to be the impedance underlying each test electrode (abstract) (column 1 lines 16-18).
- Regarding claim 57, Pearlman teaches the circuit means measuring the electrical characteristic by applying an alternating signal between the test electrode and at least one other electrode applied to the organic body of which the tissue forms a part (column 29 line 66- column 30 line 32).
- Regarding claim 58, Pearlman teaches the circuit means measuring the electrical characteristic by measuring voltage between each test electrode and adjacent reference electrode (column 25, lines 30-48) (column 29 line 66- column 30 line 32).
- Regarding claim 59, Pearlman teaches each test electrode measuring at a plurality of different frequencies (column 21, lines 14-28).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 38, 43, and 45-46, are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearlman as applied to claims 31, and 42 above, and further in view of Cudahy et al. (US 5184620).

- Regarding claim 38, Pearlman teaches the leads (142) to be disposed on the flexible backing of insulating material with the electrodes (141) (Figure 14), but doesn't expressly teach the leads to be covered with an insulating material. However, Cudahy teaches the electrodes to be insulated by the pad from other conductors (column 6, lines 17-20). It would have been obvious in view of Cudahy to provide insulation over the leads as well as the electrodes to prevent conductance between the wires.
- Regarding claims 43, 45, and 46, Pearlman doesn't expressly teach the reference electrode to be disposed on the flexible backing of the insulating material. However, Cudahey teaches the reference electrode to be on the same backing and that during a given measurement an adjacent test electrode can act temporarily as its reference in order to provide the best impedance measuring results (column 7, lines 7-24). It would have been obvious in view of Cudahey to provide adjacent test electrodes to act as temporary reference electrodes in order to eliminate false signals and provide the best impedance measurement.

5. Claims 49 and 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pearlman as applied to claims 31 and 50 above, and further in view of Bloom et al. (US 6963772).

- Regarding claims 49 and 60, Pearlman doesn't expressly teach the array of test elements incorporated into a wound dressing. However, Bloom teaches an impedance measuring system incorporated into a wound dressing to monitor wound healing (abstract) (column 1, lines 6-12). It would have been obvious in view of Flam to incorporate the system into a wound dressing to allow for measurements of an underlying lesion to monitor its healing without having to remove the bandage.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Flam (US 5181905) discloses a dressing with electrodes for sensing the condition of a wound under the dressing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 8:30-5:00 eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736